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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,656	08/28/2001	Arthur E. Uber III	P 265228 VI/98-013.FWC.C.	5530
909	7590	11/03/2003	EXAMINER	
PILLSBURY WINTHROP, LLP P.O. BOX 10500 MCLEAN, VA 22102			DESAUTO, MATTHEW F	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 11/03/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/939,656	UBER, ARTHUR E.
	<b>Examiner</b>	<b>Art Unit</b>
	Matthew F DeSanto	3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 19 August 2003.

2a) This action is FINAL.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 13-62 is/are pending in the application.

    4a) Of the above claim(s) 20-62 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 13-19 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
    If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a) All b) Some \* c) None of:  
     1. Certified copies of the priority documents have been received.  
     2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
     3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    \* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
    a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) Notice of References Cited (PTO-892)                    4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)                    5) Notice of Informal Patent Application (PTO-152)  
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.                    6) Other:

**DETAILED ACTION**

***Election/Restrictions***

1. Newly submitted claims 20-57 and 58-62 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:
2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 13-19, drawn to an injection apparatus with a mixing device, classified in class 604, subclass 151.
  - II. Claims 20-57 are drawn to an injection device with a connector and a first and second conveyor, classified in class 128, subclass 897.
  - III. Claims 58-62 are drawn to an injection device with a pump and a connector, classified in class 417, subclass 46.

The inventions are distinct, each from the other because of the following reasons:

3. Inventions II and I are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because of the mixing device. The subcombination has separate utility such as being used as mixing syringe for fibrin adhesive.
4. Inventions III and I are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does

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not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the mixing device. The subcombination has separate utility such as being used as mixing syringe for fibrin adhesive.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 20-62 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

#### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 13-19 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Kampfe et al. (USPN 5450847).

Kampfe et al. discloses an injection device with a first fluid source (12), a second fluid source (14), a fluid path (16, 22, 24), and a mixing device (20); as well as a metering device (26,28,30), a control unit (42), and a fluid assurance device (60,62). (Figure 1 and entire reference)

As to claims 17 and 18, wherein one of the sources is a contrast source and wherein one of the sources is a diluent source. (Column 8, line 61 – Column 9, line 65)

***Double Patenting***

The double patenting rejection has been withdrawn because of the terminal disclaimer.

***Terminal Disclaimer***

3. The terminal disclaimer filed on 8/19/03 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of USPN 5,806,519 has been reviewed and is accepted. The terminal disclaimer has been recorded.

***Response to Arguments***

4. Applicant's arguments filed 8/19/03 have been fully considered but they are not persuasive.

5. In response to applicant's argument that disposable and resusable, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed

invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

6. The examiner believes that the fluid path is capable of being disposable and reusable. The examiner disagrees with the Applicant stating that the Prior art (Kampfe et al.) fails to teach a fluid path from a first and second fluid sources and to a patient. This is taught throughout the entire reference but especially in [Column 8, line 20-25], wherein the fluid path (16) from a first and second fluid sources and to a patient [not shown](24). The examiner is interpreting the end pipe to be connected to a syringe arrangement, therefore the examiner believes that the syringe arrangement is intended to be used with a patient in mind as well as the information gathered from the specification of the Prior art and therefore the prior art would read on the claimed invention. The examiner also notes that the material used by Kampfe et al. dictates that parts of the fluid path could be reusable and disposable. Since the Kampfe et al. discloses that the end pipe can be connected to different containers, the examiner can further interpret this to mean that part of the fluid path can be a container such as a vial, thus the fluid path is disposable and reusable.

### ***Conclusion***

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F DeSanto whose telephone number is 1-703-305-3292. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 1-703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are 1-703-872-9302 for regular communications and 1-703-872-9303 for After Final communications.

*Matthew*  
Matthew DeSanto  
Art Unit 3763  
October 31, 2003

*Brian Casler*  
BRIAN L. CASLER  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700